

## **ATTACHMENT TO NOTICE OF ALLOWABILITY**

### **Applicants' After-Final Amendment**

1) Acknowledgment is made of Applicants' after-final amendment filed 09/03/10 in response to the final Office Action mailed 05/26/10.

### **Examiner's Amendment**

2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by attorney Ari Zytcer in a telephonic interview on 16 September 2010.

The instant application has been amended as indicated below.

(a) The first paragraph of the specification as amended on 02/16/10 has been amended as indicated below:

--This is a National Phase Application filed under 35 U.S.C. 371 as a national stage of PCT/IL2004/000929, filed October 10, 2004, an application claiming the benefit under 35 U.S.C. 119(e) U.S. Provisional Application No. 60/509,546, filed October 9, 2003, and claiming the benefit under 35 U.S.C. 119(e) U.S. Provisional Application No. 60/536,508, filed January 15, 2004, ~~the entire content of each of which is hereby incorporated by reference in its entirety.~~--

(b) Claims 78-80, 82 and 92 have been canceled.

(c) New claims 101 and 102 have been added as set forth below.

--Claim 101 (New). An immunizing composition comprising an immunologically acceptable adjuvant and an isolated peptide molecule comprising the amino acid

sequence of SEQ ID NO: 1, wherein the peptide molecule is conjugated to a carrier protein.

Claim 102 (New and rejoined). A method of eliciting Man-LAM-binding antibodies in a mammalian subject, the method comprising administering to said subject an immunizing amount of the composition of claim 101.--

(d) Claims 71, 81, 83-85, 93 and 94 have been amended as indicated below:

--Claim 71 (Currently amended). The molecule of claim 70, which does not bind to CS35 anti-lipoarabinomannan (LAM) mAb, 735 anti-ploy  $\alpha(2\rightarrow8)$ N-acetyl neuraminic acid mAb, and 2H1 anti-glucuronoxylomannan mAb.--

--Claim 81 (Currently amended). A kit for ~~diagnosing mycobacterial infection in a subject, the kit~~ comprising[[[:]] a molecule comprising an isolated peptide comprising an amino acid sequence comprising SEQ ID NO:1.--

--Claim 83 (Currently amended). The composition ~~vaccine~~ of claim 101 ~~82~~, wherein the isolated peptide molecule is capable of binding to anti-ManLAM antibodies.--

--Claim 84 (Currently amended). The composition ~~vaccine~~ of claim 101 ~~82~~, wherein the isolated peptide molecule does not bind to antibodies directed against lipoglycans selected from non-mannosylated and low mannosylated lipoglycans.--

--Claim 85 (Currently amended). The composition ~~vaccine~~ of claim 84, ~~which~~ wherein the isolated peptide molecule does not bind to CS35 anti-lipoarabinomannan (LAM) mAb, 735 anti-ploy  $\alpha(2\rightarrow8)$  N-acetyl neuraminic acid mAb, and 2H1 anti-glucuronoxylomannan mAb.--

--Claim 93 (Currently amended and rejoined). The method of claim 102 ~~92~~, wherein the isolated peptide ~~amino acid~~ molecule does not bind to antibodies directed against lipoglycans selected from non-mannosylated and low mannosylated lipoglycans.--

--Claim 94 (Currently amended and rejoined). The method of claim 93, wherein the isolated peptide molecule does not bind to CS35 anti- lipoarabinomannan (LAM) mAb, 735 anti-ploy  $\alpha(2\rightarrow8)$  N-acetyl neuraminic acid mAb, and 2H1 anti-glucuronoxylo-mannan mAb.--

### **Status of Claims**

**3)** Claims 66-69, 78, 79, 80-84 and 92 have been amended via the amendment filed 09/03/2010.

Claims 78-80, 82 and 92 have been canceled via this Examiner's amendment.

Claims 71, 81, 83-85, 93 and 94 have been amended via this Examiner's amendment.

New claims 101 and 102 have been added via this Examiner's amendment.

The method of use claims 102, 93 and 94, corresponding to the product of the instant claims, have been rejoined and fully examined. The restriction requirement set forth previously between inventions I and III is hereby withdrawn.

Claims 66-71, 81-85, 93, 94, 101 and 102 are pending and are under examination.

### **Terminal Disclaimer**

**4)** Acknowledgment is made of Applicants' submission of a terminal disclaimer filed 09/03/10 disclaiming the terminal portion of any patent granted on

this application, which would extend beyond the expiration date of any patent granted on the co-pending application, SN 11/630,115.

### **Objection(s) Withdrawn**

- 5)** The objection to the specification made in paragraph 7 of the Office Action mailed 09/16/09 is withdrawn in light of the amendments to the specification.
- 6)** The objection to claims 66-68, 81 and 82 made in paragraph 25 of the Office Action mailed 09/16/09 is withdrawn in light of Applicants' amendment to the claims.

### **Rejection(s) Moot**

- 7)** The provisional rejection of claim 82 made in paragraph 8 of the Office Action mailed 09/16/09 and maintained in paragraph 19 of the Office Action mailed 05/26/10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36 and 35 of the co-pending application 11630115, is moot in light of the cancellation of the claim.
- 8)** The rejection of claim 82 made in paragraph 21 of the Office Action mailed 05/26/10 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of the cancellation of the claim.
- 9)** The rejection of claim 82 made in paragraph 24 of the Office Action mailed 05/26/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 10)** The rejection of claim 82 made in paragraph 22 of the Office Action mailed 05/26/10 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is moot in light of the cancellation of the claim.

### **Rejection(s) Withdrawn**

**11)** The provisional rejection of claim 83 made in paragraph 8 of the Office Action mailed 09/16/09 and maintained in paragraph 19 of the Office Action mailed 05/26/10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36 and 35 of the co-pending application 11630115, is withdrawn in light of Applicants' submission of a terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of any patent granted on the co-pending application, SN 11/630,115.

**12)** The rejection of claims 66, 81 and those dependent therefrom made in paragraph 21 of the Office Action mailed 05/26/10 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims.

**13)** The rejection of claims 66-71, 81 and 83-85 made in paragraph 24 of the Office Action mailed 05/26/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

**14)** The rejection of claims 81 and 83-85 made in paragraph 22 of the Office Action mailed 05/26/10 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is withdrawn in light of the amendments to the claims and/or the base claim.

### **Rejoinder**

**15)** Pursuant to the procedures set forth in the *Official Gazette Notice* dated March 26, 1996 (1184 O.G. 86), a claim directed to a process of using the patentable

product(s), previously withdrawn from consideration as a result of restriction requirement, is now subject to being rejoined. The withdrawn claims 102 (corresponding to the canceled claim 92), 93 and 94, drawn to a method of using the allowable product, are hereby rejoined and fully examined for patentability under 37 C.F.R 1.104. Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, the restriction requirement between inventions I and III as set forth in the Office action mailed on 02/25/2009 is hereby withdrawn.

### **Remarks**

**16)** Claims 66-71, 81, 101, 83-85, 102, 93 and 94, now renumbered as claims 1-6, 7, 8, 9-11, 12, 13 and 14 respectively, are allowed.

New claims 101 and 102 are supported at section 'Assay 2: Eliciting an immune response' beginning at page 9 of the instant specification; lines 10-24 of page 16; last full paragraph of page 26; first full paragraph of page 27; and lines 10-24 of page 30 of the instant specification; and the canceled claims 82 and 92.

**17)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the Office's Central Rightfax number 571-273-8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.

**18)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**19)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry Helms, can be reached on (571) 272-0982.

/S. Devi/  
Primary Examiner  
AU 1645

September, 2010